PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :		(11) International Publication Number:	WO 91/09637
A61M 5/32	A1	(43) International Publication Date:	11 July 1991 (11.07.91)

(21) International Application Number: PCT/GB90/01992

(22) International Filing Date: 20 December 1990 (20.12.90)

(30) Priority data:
8928959.9 21 December 1989 (21.12.89) GB

(71)(72) Applicant and Inventor: STEER, Andrew, William [GB/GB]; 94A Bushey Hill Road, Camberwell, London SE5 8QQ (GB).

(74) Agent: COOK, A., J.; D. Young & Co., 10 Staple Inn, London WC1V 7RD (GB).

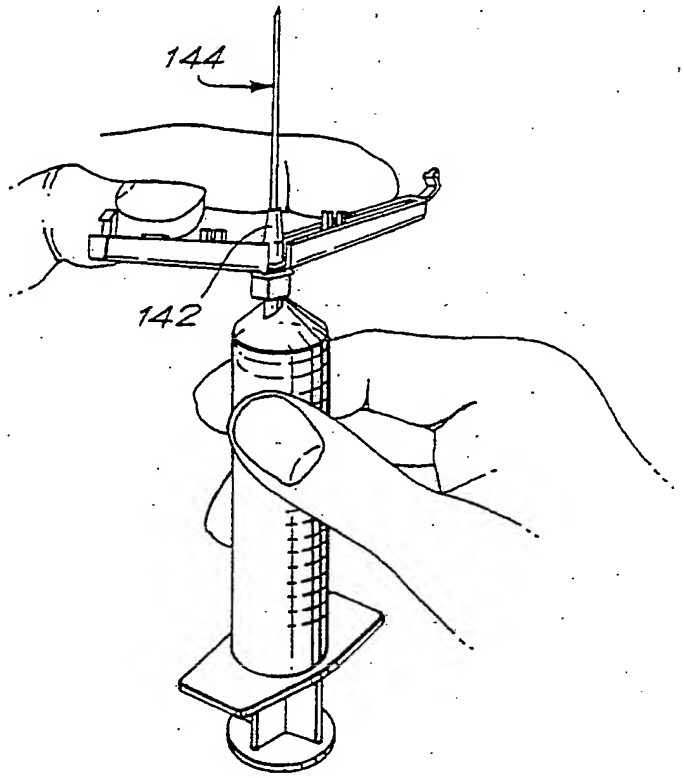
(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CM (OAPI patent), DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NL (European patent), NO, RO, SD, SE, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent), US.

Published
With international search report.

(54) Title: NEEDLE PROTECTOR

(57) Abstract

A needle protector includes a central part hingedly connected to two elongate housing parts (10, 20) for pivoting between respective open positions and a mutually closed position. In the latter they substantially encase an injection needle. The central part is constructed to interfit with a standard Luer syringe nozzle. The two housing parts are closable by a clip (400) which is moulded in one piece with the protector and joined to one housing part by an integral plastics hinge (408).



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland			SN	Senegal
CI	Côte d'Ivoire	KR	Republic of Korea	SU	Soviet Union
CM	Cameroon	LI	Liechtenstein	TD	Chad
CS	Czechoslovakia	LK	Sri Lanka	TG	Togo
DE	Germany	LU	Luxembourg	US	United States of America
DK	Denmark	MC	Monaco		

NEEDLE PROTECTOR

The present invention relates to a needle protector and to a syringe in combination with a needle protector. The invention also relates to a method of protecting the injection needle of a syringe.

Attempts have been made to protect a needle in a hypodermic syringe, so that a sterile needle is protected from contamination prior to use, or so that a patient or user is protected from infection that may result from being accidentally cut or pricked by a used needle. Problems of infection may also arise when used needles are disposed of. The need for effective protection has become much more important since the spread of AIDS.

There have been many prior proposals for needle protectors of various kinds. Examples can be seen in the following patent specifications:

Country	Number	Name	Date
U.S.	3 840 008	Noiles	1974
U.S.	4 139 009	Alvarez	1979
U.K.	2 178 322	NRDC	1987
U.S.	4 693 708	Wanderer	1987
U.S.	4 664 259	Landis	1987
E.P.	281421	Luther Medical Products Inc.	1988
U.S.	4 723 943	Spencer	1988
U.S.	4 737 144	Choksi	1988
E.P.	268445	Sterimatic Holdings Ltd.	1988
U.S.	4725267	Vaillancourt	1988
U.S.	4 735 618	Hagen	1988
PCT	WO89/07955	Habley Medical	1989
U.K.	2 215 612	Norelli	1989
EP	340892	Cole	1989
U.S.	4 838 871	Luther	1989
France	2 618 685	Brunet	1989

Several of these prior suggestions, e.g. Wanderer, Spencer, Choksi, NRDC, Stermimatic and Cole require an extra part which is attachable to or attached to or made integral with a syringe. This attachment requires the syringe to be of non-standard construction. Since manufacturers of syringes and needles have many millions of pounds invested in equipment for their high-speed mass

production, designs of needle protector which require non-standard syringes or non-standard needle hubs (e.g. the provision of pivot pins on the hub as seen at 13 in Fig. 1a of Luther '871) are commercially unacceptable and are likely to find at best only limited application. In addition, any needle protector system which requires a separate supply of protector sleeves or protector caps is likely to give rise to problems in maintaining inventories in hard-pressed hospitals. The extra manipulation required to assemble a needle protector onto the syringe means that the device will not meet the needs of busy nursing staff.

Attempts have been made, e.g. Landis '259, or Cole EP 340892 to provide a protector that protects a new sterile needle and can also serve as a safe throw-away container for a used needle. Landis however fails to fully enclose the needle because his protector has a base which is "attached to the needle hub" and from which part of the hub projects as seen in Figure 1. Hence one either needs a special non-standard needle hub structure to faciliate a permanent attachment, or one uses a push-on type of attachment which means that a used needle can readily be withdrawn endwise by gripping and pulling the exposed portion of the hub. In the Cole device, the used needle is only partly enclosed.

It would be desirable if there existed a needle protector which is a substantial improvement over prior known proposals.

According to one aspect of the present invention, a needle protector includes a central part hingedly connected to two elongate housing parts for pivoting between respective open positions and a mutually closed position in which they substantially encase an injection needle, the central part being constructed to interfit with a standard Luer syringe nozzle, and the two housing parts being closable by a clip which is moulded in one piece with the protector and joined to one housing part by an integral plastics hinge.

Preferably the closure is accomplished by latching means.

The housing parts may be integral with the central housing, and the whole protector may be made of a moulded synthetic plastics material, e.g. polypropylene.

The latching means may be a safety latch - that is, once closed it cannot be opened except by virtual destruction of the needle protector. More than one latching means may be included, this being particularly desirable for a protector intended for use with longer-than-standard needles, in which event the second latching means is located part-way along each housing part.

Within the housing parts there are preferably internal walls positioned to support a needle when the housing parts enclose it and an end wall constructed and arranged to allow entry of a syringe nozzle but prevent exit of a needle hub. The syringe may then be readily pulled off the needle end.

According to a preferred embodiment of the invention, the complementary housing parts are hinged to the central part in such a way that they can pivot towards and away from a needle contained therein in a plane occupied by the needle. In this arrangement, the safety latching means are preferably but not necessarily at the ends of the housing parts remote from the central part. The safety latching means instead could be located part-way along the elongate housing formed by the housing parts in their mutually closed condition.

The present invention also provides a method of using an injection needle in a manner which minimises infection comprising removing the needle which is substantially totally enclosed in a casing from a blister pack, inserting the nozzle of a syringe into an aperture of the casing which is constructed to snugly fit the nozzle, opening the casing by releasing a latch thereon so exposing at least the tip end of the needle, injecting the patient, closing the casing permanently by the use of a non-return latch thereon, removing the casing from the syringe nozzle, and disposing of the closed casing. The casing referred to herein is formed by the co-operating housing parts as will be better understood from the following description of Figures 1-5.

The invention will be better understood from the following non-limiting description of examples thereof given with reference to the accompanying drawings in which:-

Figures 1-5 illustrate a needle protector including an integral fastening clip. Figure 1 is a top plan view of a needle protector according to one embodiment of the invention; Figure 2 is an underplan view of the Figure 1 protector; Figure 3 is a vertical central cross-section showing the protector in an open position; Figure 4 is an end view of the protector of Figure 1; and Figure 5 is a partial central vertical cross section showing the ends of two housing parts remote from the central part and illustrating the clip 400 with its housing parts in their mutually closed position.

Figures 6 and 7 show further views of this embodiment of the invention; Figure 6 is a perspective view showing the construction of the housing part 20 seen in Figure 8. Figure 7 shows one housing part and a clip permanently attached thereto by an integral plastics hinge.

Figures 8-14 illustrate a sequence of simple steps in the use of a needle protector in accordance with Figures 1-7.

In this specification, where reference is made to a central vertical plane, it is assumed that the needle protector is laying in an open condition on a flat horizontal surface with the walls 13 and 23 extending upwardly from the respective base walls 12 and 22.

Referring now to Figures 1-5, the illustrated needle protector is integrally moulded from a synthetic plastics material such as polypropylene, and has a first housing part 10, a second housing part 20, and a central part 30. The parts 10 and 20 are connected to the part 30 by integral plastics hinges 11 and 21. The first housing part 10 has a base 12, side walls 13, and a wall 14 at its free end which carries a latch portion 15 of a latching means. A needle support structure is formed by a wall 17 which is shaped generally as a saddle. In use this wall in conjunction with the wall 27 (to be later described) locates the needle shank when the parts 10, 20 are in their mutually closed condition. The part 10 also has a low wall 16 near the hinge which helps to stiffen and reinforce the structure of the housing. This reinforcement is desirable because the walls are fairly thin, since it is important to save material in a "throw-away" product. The second housing part 20 has a base wall 22, side walls 23, and a free end wall 24. It also has a low wall 26 at the end by which it is joined to the central part 30. An intermediate saddle shaped wall 27 serves as a needle locator and support in a similar way to the wall 17. At the free end, i.e. the end remote from the central part 30, the second housing part 20 has an aperture 25 which serves as a co-operating portion of the latching means. The aperture 25 is preferably approximately rectangular as seen in Figures 1 and 2. There is a thinned portion 25a of synthetic plastics material adjacent thereto. In use, this portion is deformed by entry of the latch member 15 into the aperture 25. After entry of the latch the portion 25a tends to spring back to its

normal position, due to the resilience of the plastics from which the protector is made, so preventing or tending to prevent an opening of the coupled housing parts 10 and 20 even if the latch 15 should chance to be forced (e.g. by an accidental impact) in a direction towards the central part 30. The second housing part 20 also includes side plates 29 whose function is to assist in aligning the two housing parts when they are folded into their mutually closed condition.

As shown, the central part 30 is a simple rectangular or square cup shaped plastics member joined by integral hinges 11 and 21 to the housing parts 10 and 20. Central parts of other suitable shapes however may be employed. There is a keyhole slot 31 in the central part 30 as best seen in Figures 1 and 2. The central portion 32 of this slot is preferably circular and chosen to have a diameter such that it closely encircles the appropriate part of the tapered syringe nozzle. Slots of other shapes which permit a snug fit of the central part on the tapered syringe nozzle may also be suitable.

While it is preferred to have a keyhole slot as illustrated at 31 and 32, the invention must not be regarded as limited to this feature. A needle protector according to the invention would work almost as well if it had for example a re-entrant slot opening at one of the sides of the central part.

As seen best in Figure 3, the walls of the hole 32 are tapered at 33; this taper is preferably chosen to be the same as the angle of taper on a standard conventional syringe nozzle. This taper is commonly referred to as a Luer taper in the syringe art. Of course it will be appreciated that the purpose of providing the taper 33 of equal angle to the Luer taper is to assist in achieving a firm and snug fit between the central part 30 and the syringe nozzle. To enhance this fit, the thickness of the wall portion 34 of the central part 30 can be increased. With the construction as illustrated, this thickness would normally be around 1 mm. to 2 mm., but it can be increased to about 3 mm. to 4 mm. if desired. For larger syringes, of course different dimensions would be appropriate.

Equally, the length of the housing parts 10 and 20 and the positions of the walls 17, 27 are chosen to be appropriate to a particular standard size of a needle. For larger syringes and longer needles, clearly the dimensions of the needle protector according to the invention would be proportionately increased. For ease of gripping when closing the housing parts to protect and enclose a needle, ribs 18 and 28 respectively are included on the outer side of the housing surfaces 12 and 22. These ribs 18 and 28 are optional.

The clip portion 400 is made integral with the housing part 10. It serves to hold the two housing parts in an almost closed position in which they protect a new sterile needle (Fig. 5). At the same time however, it holds the housing parts 10 and 20 a small distance apart and prevents the latch member 15 passing sufficiently through the aperture 25 so that the hook of the latch passes and engages over the edge of the wall 24. If this occurred, it would defeat the object of this embodiment of the invention because a new sterile needle would then be trapped within the closed housing parts 10, 20. However, with the clip 400 in place, this is prevented and yet the needle protector can readily be opened to expose the new needle ready for use by pivoting the clip about its hinge. After use, the housing parts are fully closed and the latching member 15 is then passed through the aperture 25 and trapped by the deflectible part 25a. The protector (enclosing the used needle) can then be safely discarded. This clip portion 400 is illustrated in Figures 1-7. Figures 5 and 7 are partial cross-sections showing a clip portion 400 of the housing part 10 respectively in its closed and open positions. Figure 6 is a perspective view, inverted relative to Figure 5, showing the clip in its open position attached by an integral plastics hinge to the housing part 10. The clip 400 is substantially L-shaped and has limbs 402 and 404 and a lug 406 at the end of the limb 404 nearer to the integral hinge 408. A rib 410 on the outer side of the limbs 402, 404 gives the clip stiffness against deformation. The clip has a stud or rib 412 towards the free end of its limb 402 which can engage with a stud or rib 12A on the base wall 12 of the housing part 10. The interengagement of these two ribs keeps the clip portion 400 in its closed condition, and the lug 406 on the clip then prevents the latch member 15 moving to its permanently-locked position. However by flicking back the clip 400 to the position shown in Figure 6, the latch member 15 is freed to pass through the slot 25 and take up a locked position. The closed protector can then be discarded, with no fear that the infected needle can be extracted therefrom (except of course by total destruction of the protector). In the closed position of the clip 400, seen in Figure 5, it will be observed that the limb 402 and its rib 412 embrace and engage with the end of the housing part 10 and its rib 103 while the lug member 406 prevents full closure of the housing parts 10, 20.

Figures 8-14 illustrate steps in the use of the embodiment of needle protector according to Figures 1-7 herein. As seen in Figure 8, new sterile needles are contained in respective needle protectors according to the invention and these protectors are encased in a blister pack of conventional kind. Of course different sizes of blister pack will carry different numbers of needles. When it is desired to use a needle, the nurse lifts the blister pack as seen in Figure 8 and extracts the needle protector . In Figure 8 the hub 142 of the needle is visible through the open side of the central part 30 and the circular portion 32 of the keyhole slot is substantially aligned with the needle hub. As seen in Figure 9, the syringe nozzle 60 is inserted through the hole 32 and into the hub 60. During this process the sterile needle is safely encased and securely held within the needle protector. To use the syringe-needle combination to give an injection, the user flicks the clip 400 off with his or her finger or thumb (see Fig. 10) which releases the housing parts 10, 20 which pivot on the hinges 11, 21 so exposing the sterile needle 144 as seen in Figure 11. After the injection has been given (Fig. 12) the two housing parts are closed together leaving the clip 400 in its free (or open) position and by pressing them together as seen in Figure 13 the latch member 15 is caused to deform the tab 25a and pass through the aperture 25, so making an effectively non-return latching connection between the housing parts 10 and 20. Hence the used and potentially infective needle is substantially permanently enclosed within the latched housing parts and the needle protector can be removed (Fig. 14) from the syringe nozzle and discarded. It will be realisedthat the needle cannot be withdrawn longitudinally from the closed needle protector, because the maximum diameter of the needle hub is greater than the diameter of the hole 32.

The protector shown in Figures 8-14 can readily be moulded in one piece in a simple open and shut mould without side action and hence can be inexpensively produced in high volume. Use of this version allows a needle manufacturer to dispense with conventional needle packaging and wrapping, and enables inexpensive and high-speed blister packaging to be employed. In addition, as will be seen from Figures 8-14, the protector is easily manipulated at all stages, the user finds it easy to keep his or her fingers behind the needle hub, and the likelihood of pricks or punctures is greatly reduced.

In this specification, mention has been made of the feature that the needle protector is constructed to interfit with, or clip onto, the nozzle of a standard syringe. This feature is a considerable advantage and is of considerable importance to the invention, because it means that needle protectors according to the invention as disclosed herein can be used with any standard syringe and any standard needle. Hence the advantages of the invention can be enjoyed without the expense of altering the existing mass production arrangements for standard needles and syringes.

Advantages of the embodiments of the invention particularly disclosed herein are that the needle protector will fit any standard needle and syringe before use, after filling, or after use; it can serve as the package in which the sterile needles are originally supplied; it can be fitted in a manner that involves only easy manipulation and that greatly minimises risk to operator; can enclose a contaminated needle with minimum risk to operator; the resulting assembly can then be removed from a syringe, encasing the used needle and cannot be opened by ordinary means, and is totally safe for destructive disposal; the product will be very cheap in bulk supply; and is no need for the protector itself to be sterile; and it can be supplied in bulk on wards or in individual packs.

CLAIMS

1. A needle protector including a central part hingedly connected to two elongate housing parts for pivoting between respective open positions and a mutually closed position in which they substantially encase an injection needle, the central part being constructed to interfit with a standard Luer syringe nozzle, and the two housing parts being closable by a clip which is moulded in one piece with the protector and joined to one housing part by an integral plastics hinge.

2. A blister pack containing one or more needle protectors according to claim 1.

3. A needle protector according to claim 1 in which the clip is substantially C-shaped with a transverse lug adjacent its hinge to the adjacent housing part.

4. A needle protector according to claim 1 or 2 in which the clip has a stiffening rib on its outer surface.

5. A needle protector according to claim 1, 2 or 3 in which the clip, near to its free end, has a rib or pips positioned to cooperate in the closed position of the clip with a rib or pips on the base wall of that housing part to which the clip is not directly connected.

6. A method of using an injection needle in a manner which minimises infection comprising removing the needle which is substantially totally enclosed in a casing from a blister pack, inserting the nozzle of a syringe into an aperture of the casing which is constructed to snugly fit the nozzle, opening the casing by releasing a latch thereon so exposing at least the tip end of the needle, injecting the patient, closing the casing permanently by the use of a non-return latch thereon, removing the casing from the syringe nozzle, and disposing of the closed casing.

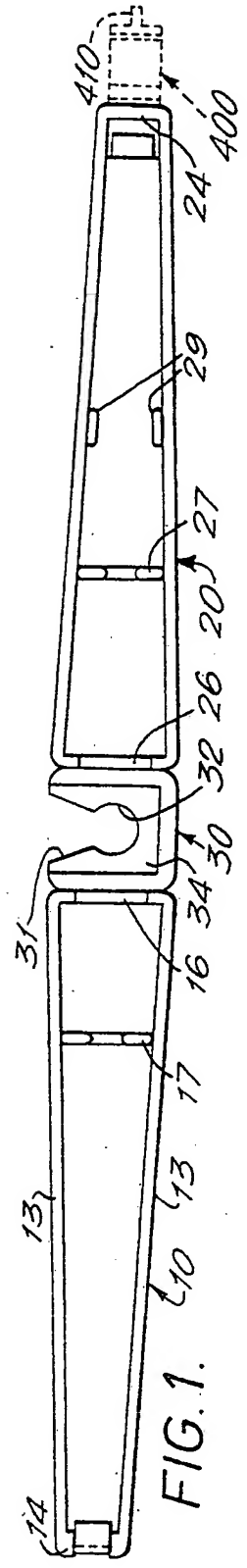


FIG. 1.

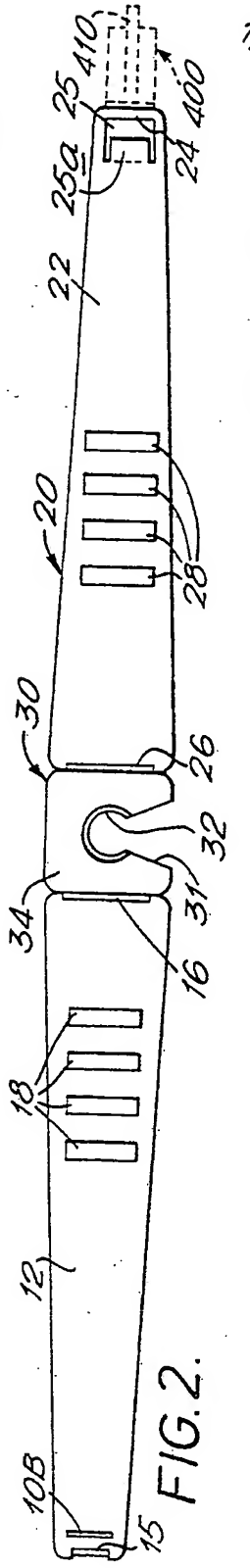


FIG. 2.

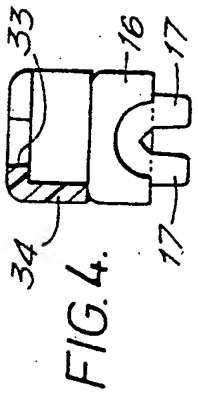


FIG. 4.

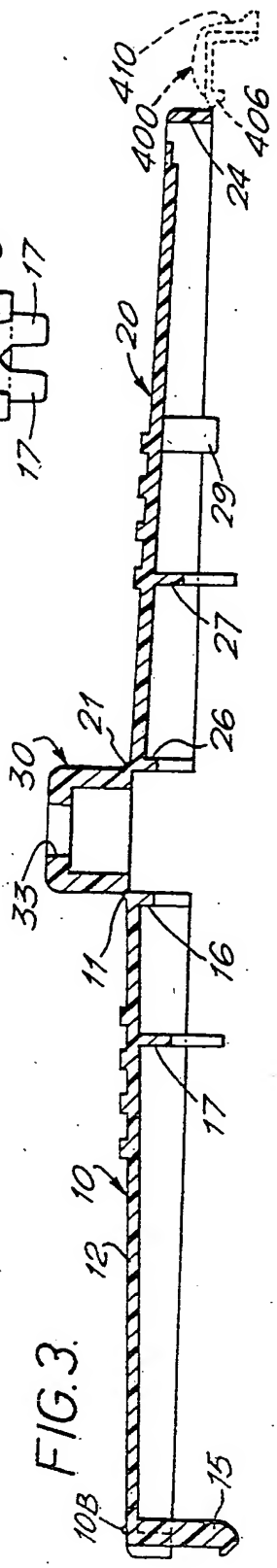


FIG. 3.

FIG.5.

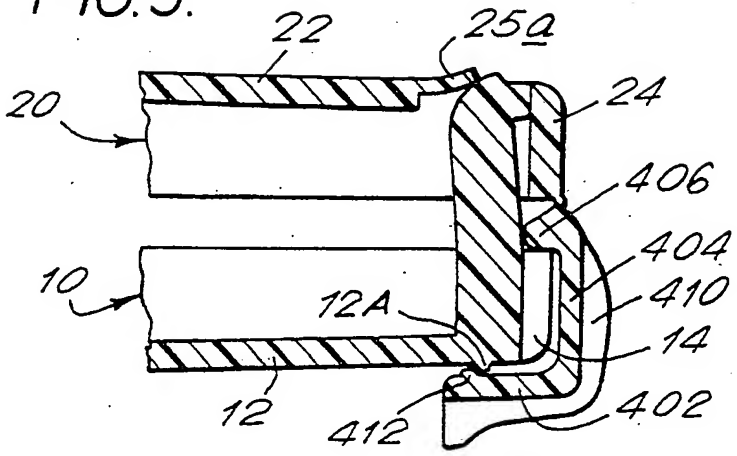

22
25a
20
24
406
404
10
410
12A
14
12
412
402

FIG.6.

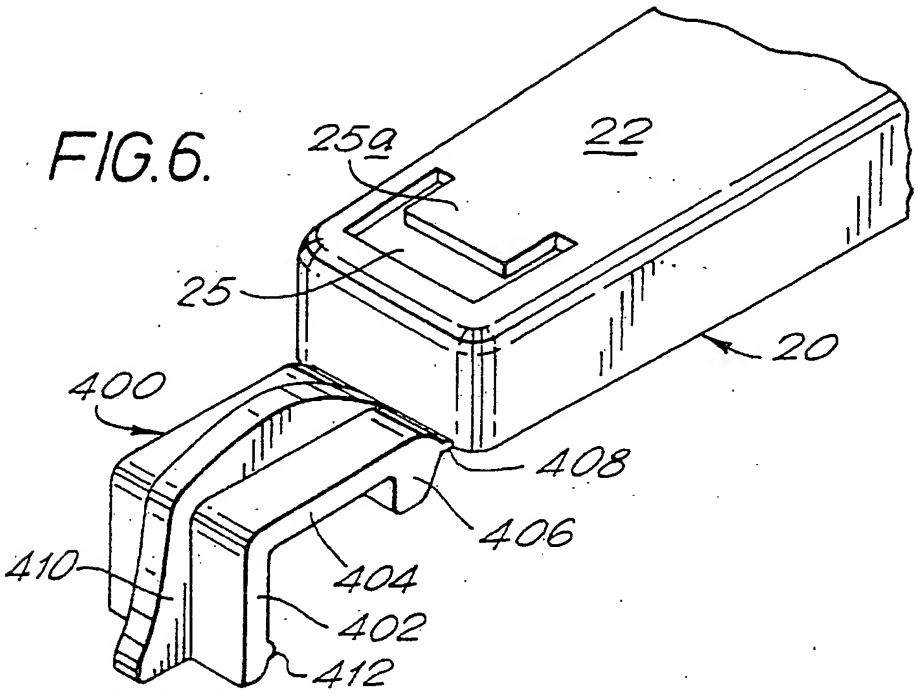

25a
22
25
20
400
408
406
410
404
402
412

FIG.7.

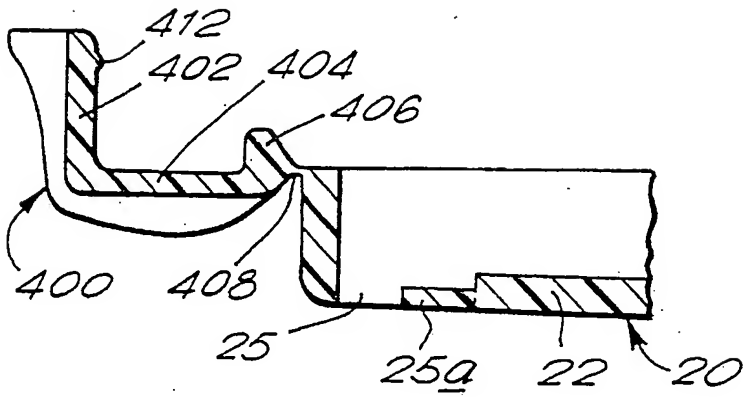


FIG.8.

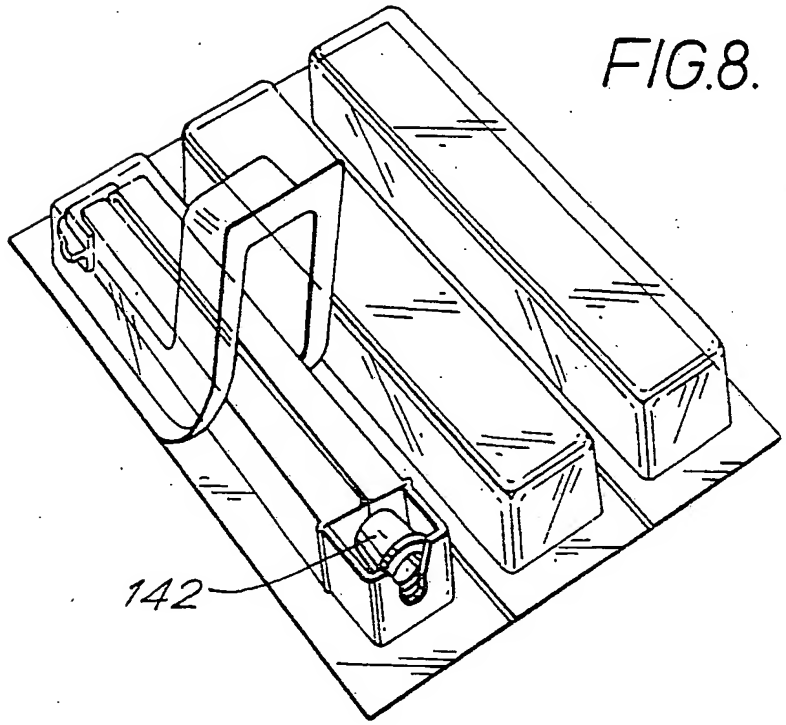
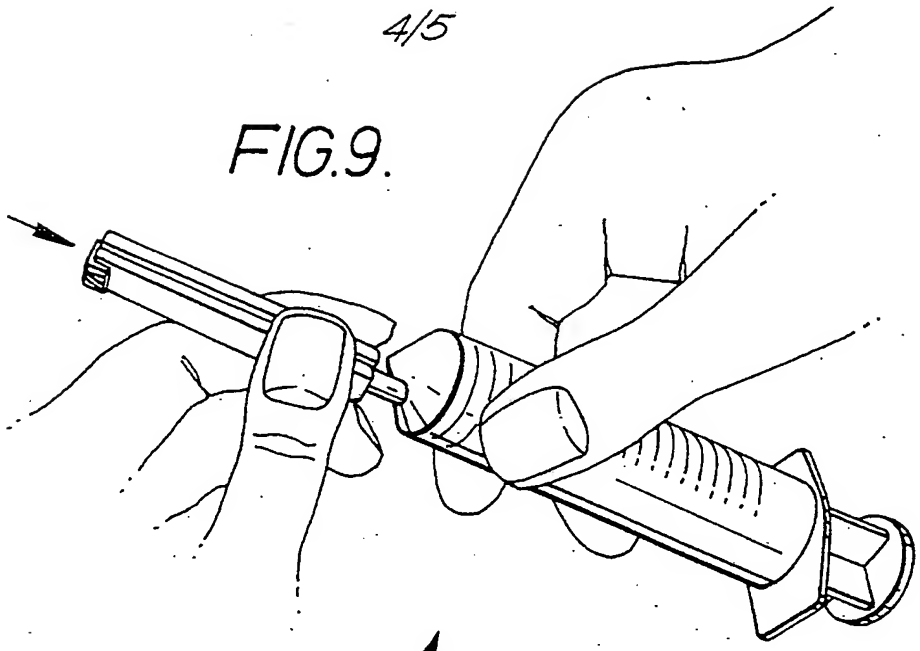


FIG.9.



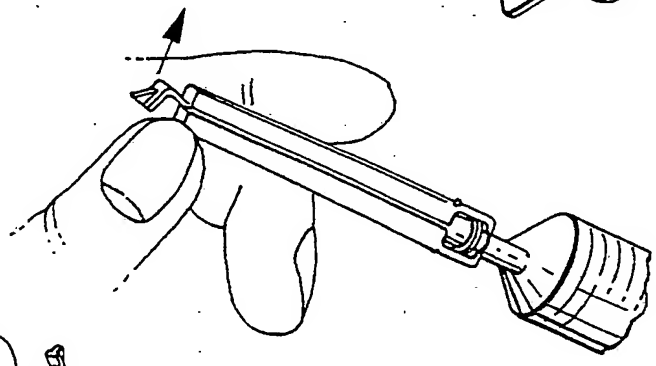


FIG.10.

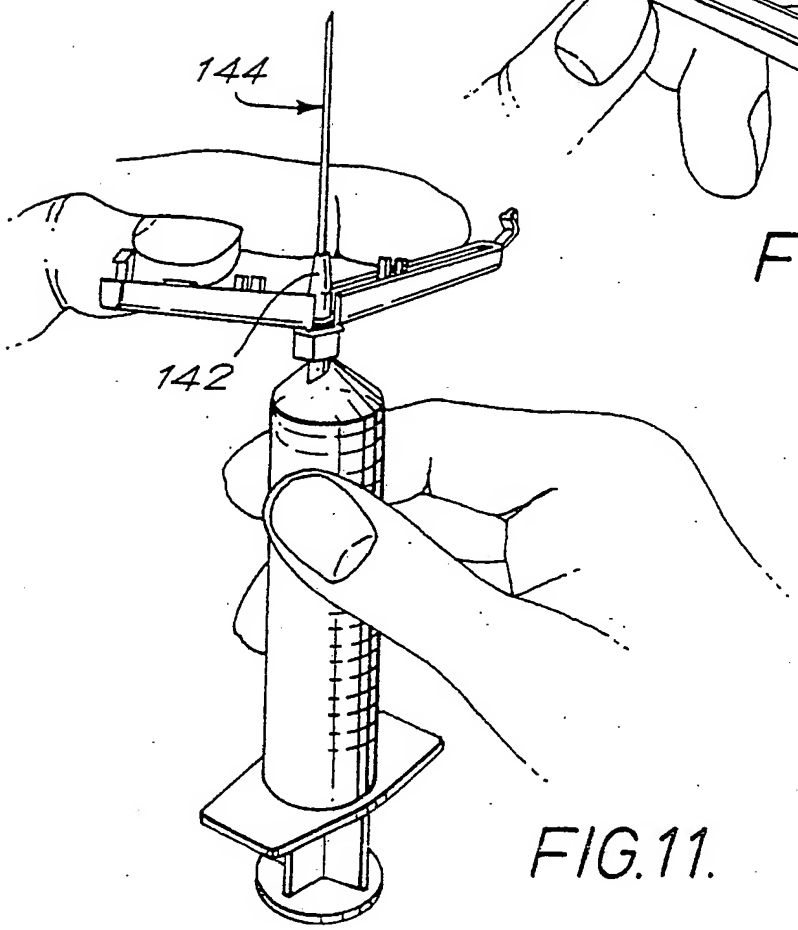
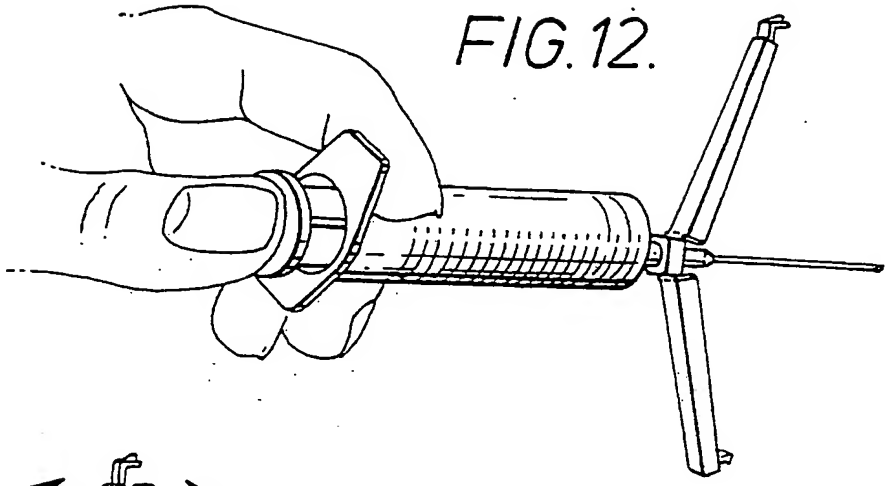


FIG.11.

FIG.12.



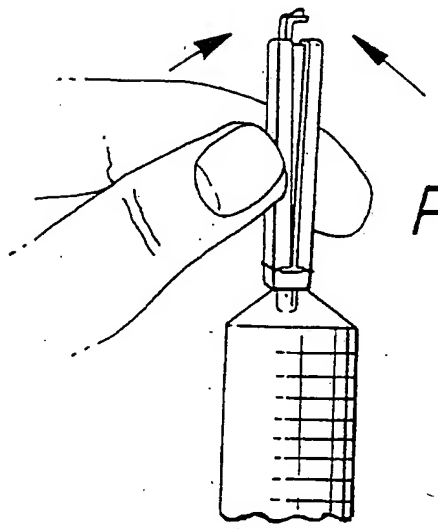


FIG.13.

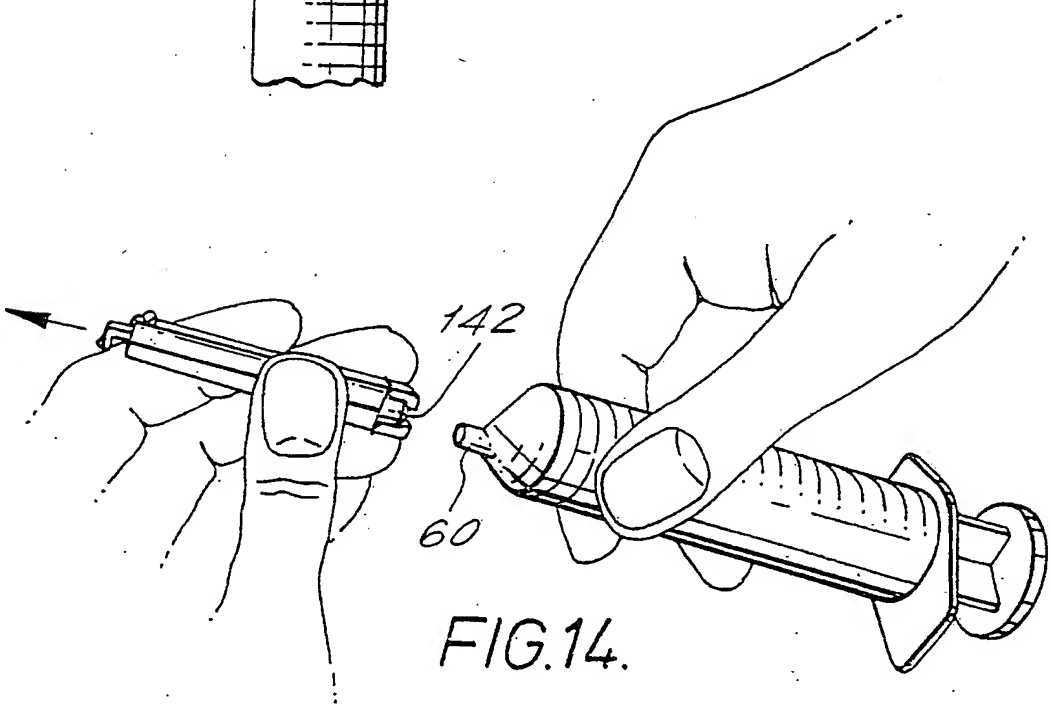


FIG.14.

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 90/01992

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[5]: A 61 M 5/32

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[5]	A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	EP, A, 0344606 (HABLEY MEDICAL TECHNOLOGY CORPORATION) 6 December 1989 see abstract; page 5, lines 2-21; claims 1,3,8; figures 1-13	6
A	--	1
Y	US, A, 3825002 (PAIGE) 23 July 1974 see abstract; column 3, lines 12-45; figure 1	6
A	--	2
A	US, A, 4888001 (SCHOENBERG) 19 December 1989 see abstract; column 1, lines 43-68; column 2, line 56 - column 3, line 53; figures 1-15	1
	--	
	./.	

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
18th March 1991	22. 04. 91
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	M. PEIS M. Peis

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	GB, A, 1447237 (SADLER) 25 August 1976 see page 1, lines 22-40; figures 1-4	1
A	US, A, 4643722 (SMITH, Jr.) 17 February 1987 see abstract; column 4, lines 30-51; figures 3-6	1
A	WO, A, 8800477 (QUAYLE) 28 January 1988 see abstract; page 14, lines 13-27; figures 15,24,25	1

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 9001992 SA 43248

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 12/04/91
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A- 0344606	06-12-89	US-A- 4935013 JP-A- 2026563	19-06-90 29-01-90
US-A- 3825002	23-07-74	None	
US-A- 4888001	19-12-89	None	
GB-A- 1447237	25-08-76	None	
US-A- 4643722	17-02-87	None	
WO-A- 8800477	28-01-88	AU-A- 7587587	10-02-88